APR 0 5 2013

510(k) Summary

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

The assigned 510(k) number is: ___k130698_____

1. Manufacturer's Name, Address, Telephone, and Contact Person, Date of Preparation

Manufacturer:	Siemens Healthcare Diagnostics Inc. 500 GBC Dr., M/S 514 P.O. Box 6101 Newark, DE 19714
Contact Information:	Siemens Healthcare Diagnostics Inc. 500 GBC Dr., M/S 514 P.O. Box 6101 Newark, DE 19714 Attn: Anna Marie Kathleen Ennis Tel: 302-631-9352 FAX # 302-631-6299
Date of Preparation:	April 5, 2013

2. Device Name

Proprietary Name

- Dimension Vista® Progesterone Calibrator (PROG CAL)

Common Name

- Calibrator

FDA Classification

- Calibrator, Secondary
- Class II
- Code JIT
- 21CFR§862.1150

3. Identification of the Predicate Device

- Siemens Healthcare Diagnostics
  Dimension Vista® LOCI 9 Calibrator – k113373
- Calibrator Secondary
- Class II
- Code JIT
- 21CFR§862.1150

4. FDA Guidance Document(s):

- "Abbreviated 510(k) Submissions for In Vitro Diagnostic Calibrators ", February 22, 1999.
- "Refuse to Accept Policy for 510(k)s", December 31, 2012.
- "eCopy Program for Medical Device Submissions", December 31, 2012

5. Device Description(s):

Calibrator
PROG CAL is a single analyte, liquid, frozen, product containing progesterone and preservatives in a human serum base, for *in vitro* diagnostic use.

Contains human source material. Each donor unit used in the preparation of this product was tested by FDA-approved methods for the presence of antibodies to Human Immunodeficiency Virus Type 1 (HIV-1) and Type 2 (HIV-2), as well as for Hepatitis B surface Antigen and antibody to Hepatitis C Virus (HCV), and found to be negative (not repeatedly reactive). Because no testing can offer complete assurance that these or other infectious agents are absent, this material should be handled using good laboratory practice to avoid skin contact and ingestion.

The kit consists of ten vials, two each of five levels containing 1 mL per vial.

The shelf life for Dimension Vista™ Progesterone Calibrator (PROG CAL) is 12 months. frozen at -15C to -25C by customers

For opened products:

Once the cap is removed, assigned values are stable for15 days, when recapped immediately after use and stored at 2-8°C.

Once the stopper of the vial is punctured by the Dimension Vista® System, assigned values are stable for 15 days when stored on board the Dimension Vista® System.

Real time calibrator shelf life is determined by comparing results of the calibrator levels stored at -15C and -25C with control calibrators stored at -70C. The Dimension Vista instrument is calibrated at each test point with -70C control calibrator. The -15C and -25C calibrator values are recovered versus the control calibration. Recovery versus time is monitored and percent change over time is determined. In addition to frozen storage condition, the calibrator levels were tested, in real time, after thawing at 2- 8°C for 15 days to claim 15 days 2-8C stability. Defined acceptance criteria were met at all conditions.

Values for the each level of calibrator are assigned to using multiple Dimension Vista instruments and multiple reagent lots calibrated with master pools whose values are traceable to the Progesterone reference method, Isotope dilution Mass Spectrometry (ID/GC/MS). The bottle value for each level is the mean of 45 replicates.

Stability testing and value assignment studies were done using the Dimension Vista® 1500 Clinical Chemistry System.

6. Device Intended Use:

Calibrator
The PROG CAL is an in vitro diagnostic product for the calibration of the Progesterone method on the Dimension Vista® System.

7. Medical device to which equivalence is claimed:

Substantial Equivalence:
The Dimension Vista® PROG CAL Calibrator (KC637) is substantially equivalent to the Dimension Vista® LOCI 9 Calibrator, (k113373) cat. # KC647.

Comparison to Predicate Device:

The proposed Siemens Healthcare Diagnostics Dimension Vista® Progesterone Calibrator (PROG CAL) and the predicate Dimension Vista® LOCI 9 Calibrator are both in vitro diagnostic products for the calibration of the Dimension Vista® Progesterone method on the Dimension Vista® System.
A comparison summary of the features of the products is included in the following table.

Calibrator:

Item	Device Progesterone Calibrator (PROG CAL)	Predicate LOCI 9 Calibrator ((k113373))
Similarities		
Intended Use	The PROG CAL is an *in vitro* diagnostic product for the calibration of the Progesterone method on the Dimension Vista® System.	The LOCI 9 CAL is an *in vitro* diagnostic product for the calibration of the progesterone (PROG) method on the Dimension Vista® System.
Traceability	Isotope Dilution gas chromatography mass spectrometry (ID/GC/MS) reference measurement procedure	Isotope Dilution gas chromatography mass spectrometry (ID/GC/MS) reference measurement procedure
Target Concentrations	Level A 0 ng/mL Level B 1.00 ng/mL Level C 8.00 ng/mL Level D 20.0 ng/mL Level E: 44.0 ng/mL	Level A 0 ng/mL Level B 1.00 ng/mL Level C 8.00 ng/mL Level D 20.0 ng/mL Level E: 44.0 ng/mL
Form	Frozen Liquid	Frozen Liquid
Differences		
Matrix	human serum base	Bovine serum base

Comments on Substantial Equivalence:
The Siemens Healthcare Diagnostics Dimension Vista® Progesterone Calibrator (PROG CAL) and Dimension Vista® LOCI 9 calibrator (LOCI 9 CAL) are both frozen liquid calibrators, traceable to the Isotope Dilution gas chromatography mass spectrometry (ID/GC/MS) reference measurement procedure for progesterone, for use in the calibration of the Dimension Vista® Progesterone assay (PROG) on the Dimension Vista® System

8. Conclusion:
The Siemens Healthcare Diagnostics Dimension Vista® Progesterone Calibrator (PROG CAL) and Dimension Vista® LOCI 9 calibrator (LOCI 9 CAL) are substantially equivalent in design and intended use.

Anna Marie Kathleen Ennis
Regulatory Affairs Manager
April 5, 2013

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 5, 2013

Siemens Healthcare Diagnostics, Inc.
C/O Anna Marie Kathleen Ennis
500 GBC Dr., M/S 514
P. O. Box 6101
NEWARK DE 19714

Re: K130698
Trade/Device Name: Dimension Vista® Progesterone Calibrator (PROG CAL)
Regulation Number: 21 CFR 862.1150
Regulation Name: Calibrator
Regulatory Class: II
Product Code: JIT
Dated: March 11, 2013
Received: March 18, 2013

Dear Ms. Ennis:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Carol C. Benson -S for

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use Form

510(k) Number (if known): K130698

Device Name: Dimension Vista® Progesterone Calibrator (PROG CAL)

Indications for Use: The PROG CAL is an in vitro diagnostic product for the calibration of the Progesterone (PROG) assay on the Dimension Vista® System.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Devices and Radiologic Health (OIR)

Yung W. Chan -S

Division Sign-Off
Office of In Vitro Devices and Radiologic Health

510(k) k130698